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SEP 3 0 2002

510(k) Summary

Date prepared 7/24/02

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 (c).

The assigned 510(k) number is K022512.

The submitter of this premarket notification is Immunicon Corporation, 3401 Masons Mill Road, Suite 100, Huntingdon Valley, PA 19006. The official correspondent is Peter J Scott, Vice President of Quality Assurance and Regulatory Affairs (215-830-0777 ext 235, fax 215-830-0751).

The subject of this summary of Safety and Effectiveness is the Immunicon *CellPrep*™ Sample Preparation System. The predicate device is the Coulter Multi-Q-Prep. The subject device is intended for use in traditional Clinical laboratories and Research Institutions. The common and classification name for this device is an Automated Blood Cell Diluting Apparatus.

The intended use for the Immunicon *CellPrep*™ Sample Preparation System is as a general-purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. Cell analyzers such as the CellTracks™ Analyzer, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for *in vitro* diagnostic use.

The CellPrep System is a semi-automated sample-handling instrument that starts with a tube of anticoagulated whole blood and delivers an enriched, processed sample that is ready to analyze by flow-cytometry, fluorescent microscopy or by the CellTracks™ Analyzer. The *CellPrep*™ System performs several steps, including red cell detection, plasma aspiration and filling of a sample chamber or test tube. The user is prompted to perform various operations such as reagent addition and mixing. The principal of operation relates to the addition of a ferrofluid, which has been conjugated with monoclonal antibodies that act with the system to magnetically separate the cells of interest and in subsequent steps, within the system, to add fluorescence-labeled monoclonals to further differentiate the captured cells. The first reagent added is

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ferrofluid, which consists of a magnetic core surrounded by a protein layer coated with antibodies for attachment to cells. Ferrofluid particles are colloidal and when mixed with a sample containing the target cells, they interact and attach to the target cells. The ferrofluid/sample mixture is placed in a strong magnetic field, which causes the labeled target cells to move to the side of the tube. The blood is aspirated, the magnetic field is removed and the cells are resuspended in a small volume of buffer and fluorescent reagents are added for the identification and enumeration of the target cells. Another magnetic separation step and resuspension is performed and the sample is now ready for analysis. The immunomagnetic enrichment process is the new technology but does not raise any new issues of safety and effectiveness.

Discussion of Clinical and nonclinical testing

Clinical testing was performed at five clinical sites by Medical technicians or degreed biologists. The clinical trial proved that the *CellPrep*™ Sample Preparation system was capable of removing small numbers of cells (~950) from a 7.5 ml volume of blood. The average recovery rate was 74.2% to 86.5% with a CV range for duplicate samples of 3.1% to 8.0%.

Nonclinical testing indicated a sensitivity of being able to recover cells at very low levels of approximately 10 cells per a 7.5 ml volume of blood and a linear recovery of cells through the range of 50 to 200 cells with a slope of 0.82 through the zero axes in a 7.5 ml sample of blood.

The *CellPrep*™ Sample Preparation System was tested and met the applicable requirements of EN 60601-1-2 (1993) "Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility requirements and Tests" and IEC 601010-2-101 "Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment".

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 0 2002

Mr. Peter Scott
Vice President of Quality Assurance
and Regulatory Affairs
Immunicon Corporation
3401 Masons Mill Road
Huntingdon Valley, Pennsylvania 19006

Re: k022512
Trade/Device Name: Immunicon *CellPrep*™ Sample Preparation System
Regulation Number: 21 CFR § 864.5240
Regulation Name: Automated Blood Cell diluting apparatus
Regulatory Class: I
Product Code: GKH
Dated: July 29, 2002
Received: July 30, 2002

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022512

Device Name: CellPrep™ Sample Preparation System

Indications For Use:

The Immunicon *CellPrep*™ Sample Preparation System is a general-purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. Cell analyzers such as the CellTracks™ Analyzer, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for *in vitro* diagnostic use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices K022512
510(k) Number

(Optional Format 3-10-98)